REMARKS/ARGUMENTS

Status of the Claims

Upon entry of the present amendment, Claims 1-7, 11, 13-18, 31-32, 77, and 82-84 are pending. Claims 1-2, 14, 77 and 82 are amended. Claims 10, 76 and 78-81 are canceled without prejudice to renewal.

Claim 1 has been amended to set forth that the amino acid sequence is at least 95% identical to SEQ ID NO:3. Support is found, for example, on page 12, lines 30-33; page 15, lines 1-4; on page 21, lines 20-27; and on page 53, lines 10-11.

Claim 2 has been amended to set forth a monoclonal antibody. Support is found, for example, on page 26, lines 13-22; page 29, lines 23-26; and on page 38, lines 20 through page 40, line 17.

Claim 14 has been amended to set forth the full text definition of the acronym "LXR." Support is found, for example, on page 2, line 16.

Claim 77 has been amended to set forth that the amino acid sequence is at least 95% identical to SEQ ID NO:3. Support is found, for example, on page 12, lines 30-33; page 15, lines 1-4; on page 21, lines 20-27; and on page 53, lines 10-11.

Claim 82 has been amended to set forth that the nucleic acid sequence is at least 95% identical to SEQ ID NO:4. Support is found, for example, on page 21, lines 20-27.

Interview with the Examiner

Applicants' agents thank the Examiner for graciously granting the telephonic interview of March 15, 2005. Proposed amendments to the claims were discussed. The Examiner suggested amending Claim 1 to set forth that the amino acid sequence is at least 95% identical to SEQ ID NO:3. The Examiner further suggested amending Claim 2 to set forth a monoclonal antibody and amending Claim 14 to set forth the full text spelling for the acronym "LXR."

Rejection under 35 U.S.C. § 112, first paragraph, enablement requirement

Claims 1, 2, 4-7, 10, 13-15, 17-18, 31-32, and 76-82 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing the enablement requirement.

In accordance with the Examiner's suggestion, Applicants have amended Claims 1 and 77 to set forth that the amino acid sequence is at least 95% identical to SEQ ID NO:3. Applicants have further amended Claim 82 to set forth that the nucleic acid sequence is at least 95% identical to SEQ ID NO:4. In accordance with the Examiner's suggestion, Applicants have amended Claim 2 to set forth a monoclonal antibody.

A particular claim is enabled by the disclosure in an application if the disclosure, at the time of filing, contains sufficient information so as to enable one of skill in the art to make and use the claimed invention without ***undue*** experimentation. *See, e.g., In re Wands*, 8 USPQ2d, 1400 (Fed. Cir. 1988), or MPEP §2164.01. It is important to note that the possibility that some experimentation, even if such experimentation is complex or extensive, may be required for the practice of the invention does not necessarily mean that the invention is not enabled:

> The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *See*, MPEP § 2164.01.
>
> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. MPEP § 2164.06, citing *In re Wands*, 8 USPQ2d, 1400 (Fed. Cir. 1988).

As previously discussed in the Amendment dated May 19, 2004, Applicants have provided guidance regarding how to make and to use an isolated nucleic acid encoding an ATP-binding cassette (ABC) family sterol transporter polypeptide, wherein the polypeptide shares about 78% sequence identity with SEQ ID NO:3 and the nucleic acid shares about 82% sequence identity with SEQ ID NO:4. Therefore, Applicants have also shown how to make and to use an ATP-binding cassette (ABC) family sterol transporter polypeptide, wherein the

polypeptide shares at least 95% sequence identity with SEQ ID NO:3 and the nucleic acid shares at least 95% sequence identity with SEQ ID NO:4. The amount of experimentation to determine which nucleotides to change is not undue, because, as Applicants teach and as was understood in the art at the time of the April 18, 2000 priority date for the present invention, well known methodologies including microarrays comprising EST libraries, standard cloning techniques, public sequence databases and alignment algorithms were used that could identify interspecies homologues and variants of nucleic acids encoding ATP-binding cassette (ABC) family sterol transporter polypeptides. Those of skill in the art were regularly using such methodologies to carry out routine screening that could identify substantially similar sequences sharing at least 95% sequence identity to SEQ ID NO:3 and SEQ ID NO:4 with a reasonable expectation of success. *In vitro* assays to determine cholesterol transport function can easily be set up for large scale routine screening, similarly to what was done to screen for monoclonal antibodies in *Wands*, for instance, by using 96-well plates (*see*, page 52, lines 26-31).

Amended Claim 2 now sets forth that the polypeptide specifically binds to a monoclonal antibody generated against a polypeptide that comprises an amino acid sequence as set forth in SEQ ID NO:3. Claim 2 is also dependent from, and therefore incorporates all of the language of Claim 1. By definition, identical monoclonal antibodies bind to a common epitope. Similar to Claim 1, Claim 2 allows for routine screening to be carried out of amino acid sequences comprising an ATP-binding cassette (ABC) family sterol transporter that share 95% sequence identity to SEQ ID NO:3 to determine if they specifically bind to a monoclonal antibody generated against a polypeptide that comprises an amino acid sequence as set forth in SEQ ID NO:3. This could be carried out using ELISA techniques, well known in the art at the time of the April 18, 2000 priority date of the present invention (*see*, page 27, lines 18-22 of the specification).

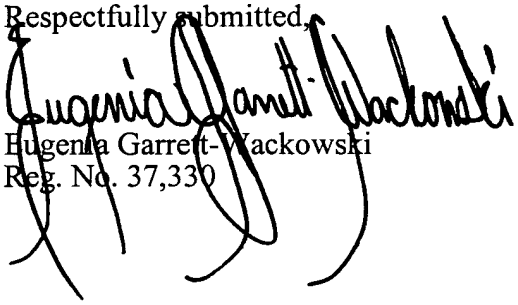
In view of the foregoing amendments and remarks, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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